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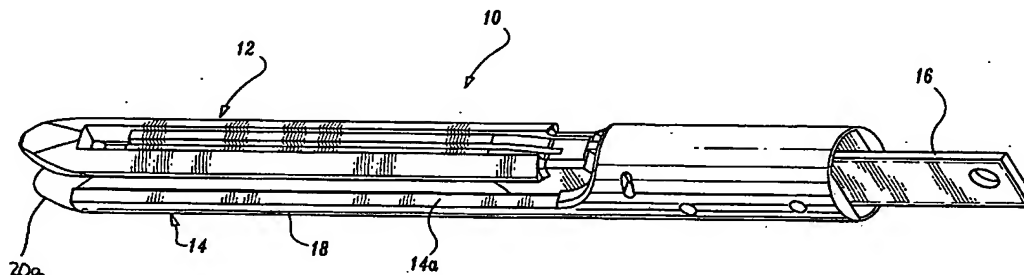
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(54) Title: TOOL ASSEMBLY FOR SURGICAL STAPLING DEVICE



(57) Abstract: A tool assembly having a pair of jaws is disclosed. Each of the jaws has a proximal end and a distal end and the first jaw is movable in relation to the second jaw between a spaced position and an approximated position. First and second cam followers are supported on the first jaw. An approximation member is movable in relation to the first jaw and includes at least one cam surface positioned to engage the first and second cam followers. The approximation member is movable in relation to the first jaw to move the at least one cam surface in relation to the first and second cam followers to effect movement of the first and second jaws from the spaced position to the approximated position. The at least one cam channel is configured to approximate the distal ends of the first and second jaws prior to approximation of the proximal ends of the first and second jaws. In another preferred embodiment, the tool assembly includes an articulation and firing actuator. The articulation and firing actuator includes a flexible band having a first end portion extending at least partially through the body portion and through the cartridge assembly, a central portion extending from the first end portion operably associated with the dynamic clamping member and a second end portion extending from the central portion through the cartridge assembly and at least partially through the body portion to a position adjacent the first end. The articulation and firing actuator is operably associated with the tool assembly such that movement of either the first end portion or the second end portion of the flexible band proximally and independently of the other end portion effects pivoting of the tool assembly in relation to the body portion, and movement of both the first and second end portions of the flexible band simultaneously effects movement of the dynamic clamping member to eject the staples from the cartridge assembly.

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**TOOL ASSEMBLY FOR SURGICAL STAPLING DEVICE**

This application claims priority from U.S. Provisional application Serial No. 60/416,056, entitled Tool Assembly For Surgical Stapling Device and filed October 4, 2003, the entire contents of which are incorporated herein by reference.

**BACKGROUND**

1. **Technical Field**

The present disclosure relates generally to a surgical tool assembly for manipulating and/or applying fasteners to tissue. More specifically, the present disclosure relates to a surgical tool assembly having a pair of jaws including a unique approximation mechanism to facilitate improved clamping and manipulation of tissue.

2. **Background of Related Art**

Surgical staplers and tool assemblies for clamping tissue between opposed jaw structure of a tool assembly and thereafter fastening the clamped tissue are well known in the art. These devices may include a knife for incising the fastened tissue. Such staplers having laparoscopic or endoscopic configurations are also well known in the art. Examples of endoscopic surgical staplers of this type are described in U.S. Patent Nos. 6,330,965, 6,250,532, 6,241,139, 6,109,500 and 6,079,606, all of which are incorporated herein by reference in their entirety.

Typically, such staplers include a tool member or assembly having a pair of jaws including a staple cartridge for housing a plurality of staples arranged in at least two laterally spaced rows and an anvil which includes a plurality of staple forming pockets for receiving and forming staple legs of the staples as the staples are driven from the cartridge. The anvil and cartridge are pivotally supported adjacent each other and are

pivotable in relation to each other between open and closed positions. In use, tissue is positioned between the jaws in the open position and the jaws are pivoted to the closed position to clamp tissue therebetween.

One problem associated with conventional staplers and tool assemblies is that as the anvil and cartridge pivot in relation to each other, closure occurs first at the proximal end of the jaws and thereafter at the distal end of the jaws. This sequence of jaw closure has the effect of moving tissue positioned between the jaws towards the distal end of the jaws, thus, forcing tissue from the jaws.

During laparoscopic or endoscopic procedures, access to a surgical site is achieved through a small incision or through a narrow cannula inserted through a small entrance wound in a patient. Because of the limited area available to access the surgical site, endoscopic staplers are sometimes used to grasp and/or manipulate tissue. Conventional staplers having an anvil or cartridge mounted to a fixed pivot point which are pivotable to a closed position are not particularly suited for grasping tissue because only a limited clamping force is produced at the distal end of the jaws.

Accordingly, a need exists for an endoscopic surgical stapling tool member or assembly having pivotal jaws which can be operated to effectively grasp, manipulate and/or fasten tissue, including with the end of the jaws, without, or while minimizing, distal movement of the tissue positioned between the jaws.

### **SUMMARY**

In accordance with the present disclosure, a tool assembly having a pair of jaws is disclosed. Each of the jaws has a proximal end and a distal end and the first jaw is movable in relation to the second jaw between a spaced position and an approximated

position. First and second cam followers are supported on the first jaw. An approximation member is movable in relation to the first jaw and includes at least one cam surface positioned to engage the first and second cam followers. The approximation member is movable in relation to the first jaw to move the at least one cam surface in relation to the first and second cam followers to effect movement of the first and second jaws from the spaced position to the approximated position. The at least one cam channel is configured to approximate the distal ends of the first and second jaws prior to approximation of the proximal ends of the first and second jaws. By approximating the distal ends of the first and second jaws first, tissue positioned between the jaws is not pushed forward within the jaws during closure of the jaws. Further, the jaws are better able to grip and manipulate tissue using the distal ends of the jaws.

Preferably, the first jaw includes an anvil and the second jaw includes a cartridge assembly housing a plurality of staples. In a preferred embodiment, the at least one cam surface includes first and second cam channels, and the approximation member includes a flat plate having the cam channels formed therein. The first jaw includes a longitudinal slot formed in its proximal end and the approximation member is being slidably positioned in the longitudinal slot. The first and second cam followers are supported on the proximal end of the first jaw and extend across the longitudinal slot adjacent the first and second cam channels. The first cam follower extends through the first cam channel and the second cam follower extends through the second cam channel. Preferably, the tool assembly is pivotally attached to a body portion by an

articulation joint. The body portion may form the distal end of a surgical stapling device or a proximal portion of a disposable loading unit.

In another preferred embodiment, the tool assembly includes an anvil, a cartridge assembly housing a plurality of staples and a dynamic clamping member. The anvil and cartridge assembly are movable in relation to each other between spaced and approximated positions. The dynamic clamping member is movable in relation to the anvil and the cartridge assembly to eject the staples from the cartridge assembly. The tool assembly is pivotally attached to a body portion and is pivotable in relation to the body portion from a position aligned with the longitudinal axis of the body portion to a position oriented at an angle to the longitudinal axis of the body portion. An articulation and firing actuator extends at least partially through the body portion and the tool assembly. The articulation and firing actuator is operably associated with the dynamic clamping member and the tool assembly and is movable in relation thereto to selectively pivot the tool assembly in relation to the body portion and/or move the dynamic clamping member in relation to the tool assembly to eject the staples from the cartridge.

Preferably, the articulation and firing actuator includes a flexible band having a first end portion extending at least partially through the body portion and through the cartridge assembly, a central portion extending from the first end portion operably associated with the dynamic clamping member and a second end portion extending from the central portion through the cartridge assembly and at least partially through the body portion to a position adjacent the first end. The articulation and firing actuator is operably associated with the tool assembly such movement of either the first end portion or the second end portion of the flexible band proximally and independently of

the other end portion effects pivoting of the tool assembly in relation to the body portion, and movement of both the first and second end portions of the flexible band simultaneously effects movement of the dynamic clamping member to eject the staples from the cartridge assembly. In a preferred embodiment, an approximation member is operably associated with the tool assembly and is movable in relation to the tool assembly to move the anvil and cartridge assembly from the spaced to the approximated position.

### **Brief Description Of The Drawings**

Various preferred embodiments of the presently disclosed tool assembly for use with a surgical stapling device are disclosed herein with reference to the drawings, wherein:

FIG. 1 is a side perspective view of one preferred embodiment of the presently disclosed tool assembly in the approximated position;

FIG. 2 is a side view of the tool assembly shown in FIG. 1;

FIG. 3 is a side, exploded perspective view of the tool assembly shown in FIG. 1;

FIG. 4A is a schematic view of the jaws of the tool assembly shown in FIG. 1 at a first stage of jaw approximation;

FIG. 4B is a schematic view of the jaws shown in FIG. 4A at a second stage of jaw approximation;

FIG. 4C is a schematic view of the jaws shown in FIG. 4B in an approximated position;

FIG. 5 is a side perspective view of another preferred embodiment of the presently disclosed tool assembly in the approximated position;

FIG. 6 is a side, exploded perspective view of the tool assembly shown in FIG. 5;

FIG. 7 is a side perspective view of the approximation member of the tool assembly shown in FIG. 6;

FIG. 8 is a side perspective view of the dynamic clamping member of the tool assembly shown in FIG. 6;

FIG. 9 is a top partial cross-sectional view with portions broken away looking through a portion of the cartridge assembly and showing the articulation and firing actuator of the tool assembly shown in FIG. 6; and

FIG. 10 is a cross-sectional view with portions removed and portions added, as would be seen along section lines 10-10 of FIG. 9.

#### **Detailed Description Of Preferred Embodiments**

Preferred embodiments of the presently disclosed tool assembly for a stapling device will now be described in detail with reference to the drawings in which like reference numerals designate identical or corresponding elements in each of the several views.

FIGS. 1-3 illustrate one preferred embodiment of the presently disclosed tool assembly shown generally as 10 for use with a surgical stapling device. Tool assembly 10 includes a pair of jaws including an anvil 12 and a cartridge assembly 14 and an approximation member 16. Cartridge assembly 14 includes a support channel 18 for receiving a staple cartridge 14a. Support channel 18 includes distal open channel portion 18a and a proximal portion 18b defining a truncated cylinder 18c. Although not shown in detail, staple cartridge 14a houses a plurality of staples and can include conventional pushers (not shown) for translating movement of a staple drive assembly

that typically includes a sled (e.g., 131 in FIG. 6) to movement of the staples through openings or slots in a tissue engaging surface 25 of cartridge 14a.

Anvil 12 has a tissue engaging surface 20 having a distal end 20a and a proximal end 20b and a proximal body portion 22. A longitudinal slot 24 extends along the central longitudinal axis of anvil 12 through tissue engaging surface 20 and is dimensioned to slidably receive a portion of a drive assembly. The drive assembly typically includes a drive bar, a closure assembly, a sled, and a plurality of pushers. The drive assembly functions to eject staples from the cartridge and preferably also maintains a desired uniform tissue gap between the cartridge and the anvil during firing of the device. Proximal body portion 22 of anvil 12 is dimensioned to be generally pivotably received within truncated cylinder 18c of proximal portion 18b of support channel 18 such that tissue engaging surface 20 of anvil 12 is pivotable from a position spaced from tissue engaging surface 25 of cartridge 14a to an approximated position in juxtaposed alignment therewith.

Tool assembly 10 includes an approximation member 16 having one or more cam channels 28 and 30. Preferably, approximation member includes a pair of cam channels although a single cam channel having a pair of cam surfaces is envisioned. Approximation member 16 is dimensioned to be linearly slidable through proximal portion 18b of channel 18 and through a slot 22a formed in proximal body portion 22 of anvil 12. A cam follower 32 extends through a bore 34 formed in proximal portion 22 of anvil 12 and through a hole 35 in proximal portion 18b of support channel 18 and is positioned within cam channel 28. A cam follower 36 extends through a second bore 38 formed in the proximal portion 22 of anvil 12 and through a hole 39 in proximal portion



and is positioned within cam channel 30. When approximation member 16 is advanced through slot 22a in proximal portion 22 of anvil 12, cam followers 32 and 36 move through cam channels 28 and 30, respectively. Since approximation member 16 is confined to linear movement within slot 22a, movement of approximation member 16 in a distal direction effects pivotal movement of anvil 12 from the open or spaced position to the closed or approximated position. The angles of the cam slots can be configured to provide a great variety of approximation motions to improve mechanical advantage and achieve specific results, e.g., grasping of tissue.

Referring also to FIGS. 4A-4C, cam channels 28 and 30 preferably are configured to pivot anvil 12 from an open position (FIG. 4A) towards cartridge assembly 14 in a controlled manner to initially facilitate grasping of tissue and thereafter provide for substantially parallel closure of the anvil and cartridge assembly. More specifically, cam channels 28 and 30 are preferably configured to position the distal end 20a of tissue contact surface 20 of anvil 12 substantially in contact with cartridge 14 (FIG. 4B) during the initial portion of an actuating stroke of approximation member 16. This facilitates grasping of tissue even very thin tissue. During a second portion of the actuating stroke of approximation member 16, distal end 20a of anvil 12 is moved away from cartridge assembly 14 to a resultant position in which tissue engaging surface 20 of anvil 12 is parallel or substantially parallel to tissue engaging surface 25 of cartridge assembly 14. During the final portion of the actuating stroke of approximation member 16, the anvil 12 and cartridge assembly 14 are brought together in parallel or substantially parallel closure to define a desired tissue gap (FIG. 4C). It is noted that any desired motion of anvil 12 can be achieved using the cam followers described

herein. By moving anvil 12 in relation to cartridge assembly 14 from the spaced to the approximated position in the manner described above i.e., front or distal to back or proximal closure, the tendency for tissue to move forward within the jaws, as in conventional devices, is substantially eliminated.

Although approximation member 16 is illustrated as being in the form of a plate with two distinct cam channels, differently configured approximation members are envisioned. For example, a single cam channel may be provided to engage two cam followers. Further, the cam channels need not be confined but rather can be formed on the surface of a plate, bar or the like. In such a device, the anvil may be urged by a biasing member to the closed or clamped position.

Although one or more actuators has not been disclosed to advance the approximation member and/or fire staples from the cartridge assembly, it is envisioned that one or more of a variety of known pivotable, rotatable, or slidable actuators, e.g., trigger, knob, lever, etc., may be used to approximate the presently disclosed cartridge assembly and/or fire staples from the cartridge. It is also noted that the disclosed tool assembly may be or form the distal portion of a disposable loading unit or may be incorporated directly into the distal end of a surgical instrument, e.g., surgical stapler, and may include a replaceable cartridge assembly.

FIGS. 5-10 disclose another preferred embodiment of the presently disclosed tool assembly shown generally as 100. Tool assembly 100 includes an anvil 112 and a cartridge assembly 114, an approximation member 116, and an elongated body portion 120 including an articulation joint generally referred to as 122. Elongated body portion 120 may form the proximal end of a disposable loading unit or the distal end of a

surgical stapling device. Tool assembly 100 also includes a combined articulation and firing actuation mechanism 124 for articulating tool assembly 100 about articulation joint 122 and ejecting staples from cartridge assembly 114. Although the articulation joint illustrated as a flexible corrugated member with preformed bend areas, articulation joint 122 may include any known type of joint providing articulation, e.g., pivot pin, ball and socket joint, a universal joint etc.

Approximation member 116 is substantially similar to approximation member 16 and also includes cam channels 128 and 130 (FIG. 7). Approximation member 116 further includes a pair of guide channels 126. Guide channels 126 are dimensioned to receive guide pins 128 which extend through elongated body portion 120 and function to maintain approximation member 116 along a linear path of travel. Approximation member 116 is constructed from a flexible material, e.g., spring steel, which is capable of bending around articulation joint 122. Alternately, it is envisioned that approximation member 116 may include a resilient rod, band or the like with cam surfaces formed thereon. Approximation member 116 operates in substantially the same manner as approximation member 16 and will not be discussed in further detail herein.

Cartridge assembly 114 includes a support channel 118, a sled 131 and a dynamic clamping member 132 which, preferably, includes an upper flange 134a for slidably engaging a bearing surface of the anvil and lower flange 134b for slidably engaging a bearing surface of the cartridge. A knife blade 134 is preferably supported on a central portion 134c of dynamic clamping member 132 to incise tissue. Knife blade may be secured to dynamic clamping member 132 in a removable or fixed fashion, formed integrally with, or ground directly into dynamic clamping member 132. Sled 131

is slidably positioned to translate through cartridge 114 in a known manner to eject staples from the cartridge. Sled 131 or the like can be integral or monolithic with dynamic clamping member 132. Sled 131 is positioned distal of and is engaged and pushed by dynamic clamping member 132. The position of 131 is to effect firing or ejection of the staples to fasten tissue prior to cutting the stapled tissue. Flange 134b preferably is positioned within a recess 138 formed in the base of cartridge 114. Flange 134a is preferably positioned within a single or separate recess formed in anvil 112. Again, flanges 134a and 134b need not be positioned in a recess but can slidably engage a respective surface of the anvil and cartridge. Dynamic clamping member 132 preferably is positioned proximal of sled 130 within cartridge assembly 114. Dynamic clamping member 132 functions to provide, restore and/or maintain the desired tissue gap in the area of tool assembly 100 adjacent sled 130 during firing of staples.

It is preferred that the anvil and preferably the dynamic clamping member be formed of a material and be of such a thickness to minimize deflection of the anvil and dynamic clamping member during firing of the device. Such materials include surgical grade stainless steel. The anvil is preferably formed as a solid unit. Alternatively, the anvil may be formed of an assembly of parts with conventional components.

Referring to FIGS. 6, 9 and 10, articulation and firing mechanism 124 includes a tension member 140 which can have loops 124 or other connection portions or connectors for connection to suitable connection members of one or more actuators or of an actuation mechanism. Although illustrated as a flexible band, tension member 140 may be or include one or more of any flexible drive member having the requisite strength requirements and being capable of performing the functions described below,

e.g., a braided or woven strap or cable, a polymeric material, a para-aramid such as Kevlar™, etc. Kevlar™ is a trade designation of poly-phenyleneterephthalamide commercially available from DuPont. A pair of suitable fixed or rotatable members, preferably rollers 142a and 142b, are secured at the distal end of cartridge assembly 114. Rollers 142a and 142b may be formed or supported in a removable cap 114b (FIG. 6) of cartridge assembly 114. Alternately, cap 114b may be formed integrally with staple cartridge 114a or cartridge channel 118. Rollers 142a and 142b can also be secured to or formed from cartridge support channel 118. Tension member 140 extends distally from elongated body 120 of tool assembly 100, distally through a peripheral channel 142 in staple cartridge 114a, around roller 142a, proximally, preferably, alongside central longitudinal slot 144 formed in cartridge 114a, through a slot 200, preferably a transverse slot, in or around a proximal portion of dynamic clamping member 132, distally around roller 142b, and again proximally through a channel 146 formed in cartridge 114a to a proximal portion of elongated body 120. Alternately, two tension members can be employed, each of which may be secured to dynamic clamping member 132. As illustrated in FIG. 10, channels 142 and 146 can be at least partly defined by an inner and/or outer wall of cartridge 114a and/or by cartridge support channel 118. Unlike as shown, channels 142 and 146 should be in a consistent, i.e., same, functionally same or corresponding location on both sides of the staple cartridge. Thus, it is envisioned that there would be two peripheral channels 142, or two channels 146.

In use, when a first end or portion 150 of tension member 140 is retracted by suitable means in the direction indicated by arrow "A", as viewed in FIG. 9, tool

assembly 100 will articulate about pivot member 122a in the direction indicated by arrow "D". When second end or portion 152 of tension member 140 is retracted in the direction indicated by arrow "B", tool assembly 100 will articulate in the direction indicated by arrow "C". When both ends of tension member 140 are retracted simultaneously, tension member 140 will advance dynamic clamping member 132 distally through slot 144 in cartridge 114a to advance dynamic clamping member 132 and sled 130 through cartridge 114a and by engaging pushers, eject staples from the cartridge and incise tissue in the tissue gap. In order to prevent dynamic clamping member 132 from advancing through slot 144 when the tool assembly is being articulated, i.e., when only one end of tension member 140 is retracted, a lockout device (not shown), e.g., a shear pin, may be provided to prevent movement of the dynamic clamping member or delay it until a predetermined force has been applied to the dynamic clamping member. It is envisioned that multiple tension members, e.g., bands, can be employed, respectively, to perform individual or a combination of functions. For example, a pair of tension members can be employed, one to articulate, and the other to approximate, clamp and fire. The tension members can be fixed to the dynamic clamping member or a knife carrying member or to a combination dynamic clamping member, knife member and/or sled member.

The above-described tool assembly may be incorporated into a disposable loading unit such as disclosed in U.S. Patent No. 6,330,965 or attached directly to the distal end of any known surgical stapling device. Although a handle assembly for actuating the approximation member and the combined articulation and firing mechanism have not been specifically disclosed herein, it is to be understood that the

use of a broad variety of different actuating mechanisms and handle configurations are envisioned including toggles, rotatable and slidable knobs, pivotable levers or triggers, pistol grips, in-line handles, remotely operated systems and any combination thereof.

The use of an above-described tool assembly as part of a robotic system is envisioned.

It will be understood that various modifications may be made to the embodiments disclosed herein. For example, although this application focuses primarily on the use of surgical staples, other fastening devices, such as two-part fasteners, may be included in this device. In a device in which two-part fasteners are used, each of the anvil staple forming pockets may be configured to receive one part of the two-part fastener. Further, it is envisioned that the teachings provided in this disclosure may be incorporated into surgical devices other than stapling devices including graspers. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

**WHAT IS CLAIMED IS:**

1. A tool assembly comprising:  
  
a pair of jaws including a first jaw and a second jaw, each of the jaws having a proximal end and a distal end, at least one of the first and second jaws being movable in relation to the other of the first and second jaws between a spaced position and an approximated position.  
  
first and second cam followers supported on the at least one jaw; and  
  
an approximation member movable in relation to the at least one jaw and including at least one cam surface positioned to engage the first and second cam followers;  
  
wherein the approximation member is movable in relation to the at least one jaw to move the at least one cam surface in relation to the first and second cam followers to effect movement of the at least one of the jaws from the spaced position to the approximated position, the at least one cam channel being configured to approximate the distal ends of the first and second jaws prior to approximation of the proximal ends of the first and second jaws.
2. A tool assembly according to Claim 1, wherein the at least one jaw is the first jaw and includes an anvil and the second jaw includes a cartridge assembly, the cartridge assembly housing a plurality of staples.
3. A tool assembly according to Claim 1 or 2, wherein the at least one cam surface includes at least one cam channel.
4. A tool assembly according to Claim 3, wherein the at least one cam channel includes first and second cam channels.



5. A tool assembly according to Claim 1, wherein the approximation member includes a flat plate having the at least one cam surface formed therein.
6. A tool assembly according to Claim 5, wherein the at least one jaw includes a longitudinal slot formed in its proximal end, the approximation member being slidably positioned in the longitudinal slot.
7. A tool assembly according to Claim 6, wherein the first and second cam followers are supported on the proximal end of the at least one jaw and extend across the longitudinal slot adjacent the at least one cam surface.
8. A tool assembly according to Claim 7, wherein the at least one cam surface includes first and second cam channels, the first cam follower extending through the first cam channel and the second cam follower extending through the second cam channel.
9. A tool assembly according to Claim 1, further including a body portion, wherein the tool assembly is pivotally attached to the body portion by an articulation joint.
10. A tool assembly according to Claim 9, wherein the body portion forms the distal end of a surgical stapling device.
11. A tool assembly according to Claim 1, 9 or 10 wherein the body portion forms the proximal portion of a disposable loading unit.
12. A surgical device comprising:
  - a body portion defining a longitudinal axis;
  - a tool assembly including an anvil, a cartridge assembly housing a plurality of staples and a dynamic clamping member, the anvil and/or cartridge assembly being

movable in relation to each other between spaced and approximated positions, the dynamic clamping member being movable in relation to the anvil and the cartridge assembly to eject the staples from the cartridge assembly, the tool assembly being pivotally attached to the body portion and being pivotable in relation to the body portion from a position aligned with the longitudinal axis of the body portion to a position oriented at an angle to the longitudinal axis of the body portion; and

an articulation and firing actuator extending at least partially through the body portion and the tool assembly, the articulation and firing actuator being operably associated with the dynamic clamping member and the tool assembly and being movable in relation thereto to selectively pivot the tool assembly in relation to the body portion and/or move the dynamic clamping member in relation to the tool assembly to effect ejection of the staples from the cartridge.

13. A surgical device according to Claim 12, wherein the articulation and firing actuator includes a flexible band having a first end portion extending at least partially through the body portion and through the cartridge assembly, a central portion extending from the first end portion and being operably associated with the dynamic clamping member and a second end portion extending from the central portion through the cartridge assembly and at least partially through the body portion to a position adjacent the first end.

14. A surgical device according to Claim 13, wherein the articulation and firing actuator is operably associated with the tool assembly such that movement of either the first end portion or the second end portion of the flexible band proximally and independently of the other end portion effects articulation of the tool assembly in relation

to the body portion, and movement of both the first and second end portions of the flexible band simultaneously effects movement of the dynamic clamping member to effect ejection of the staples from the cartridge assembly.

15. A surgical device according to any of Claims 12-14, further including an approximation member operably associated with the tool assembly and being movable in relation to the tool assembly to move the anvil and cartridge assembly from the spaced to the approximated position.

16. A tool assembly according to any of the preceding claims, wherein the tool assembly comprises a disposable loading unit.

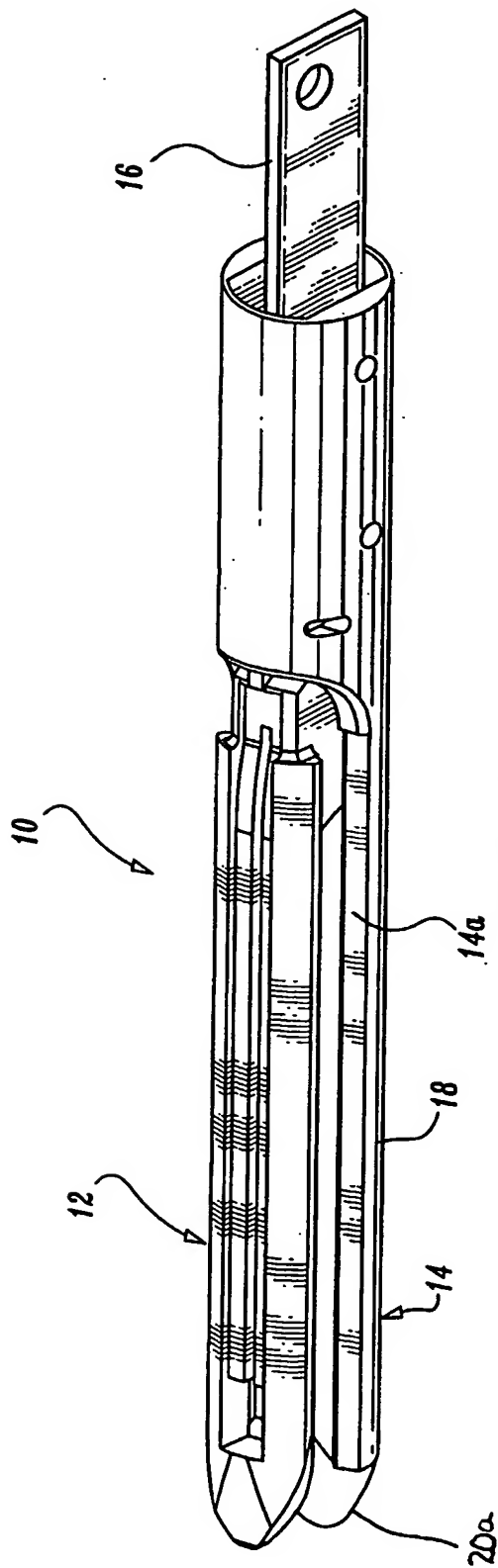


FIG. 1

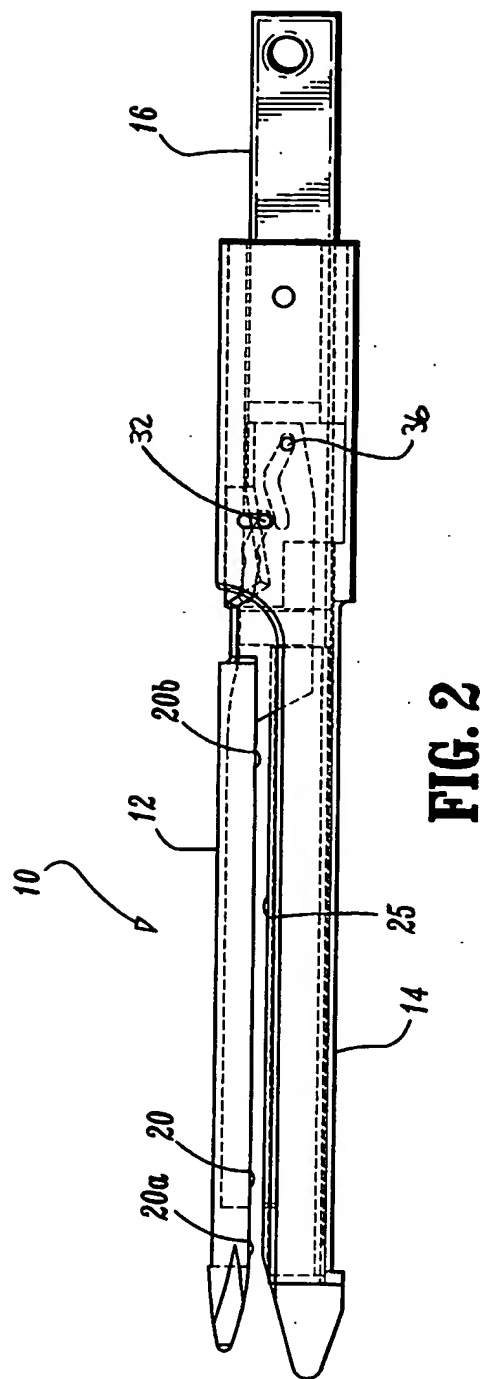
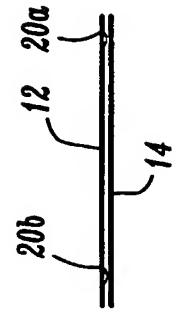
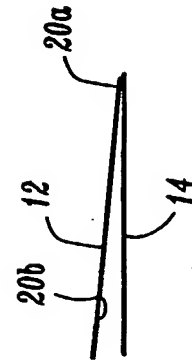
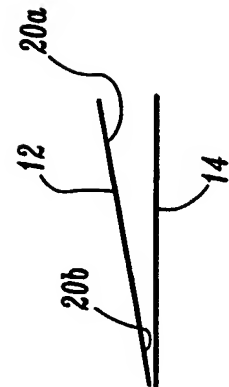
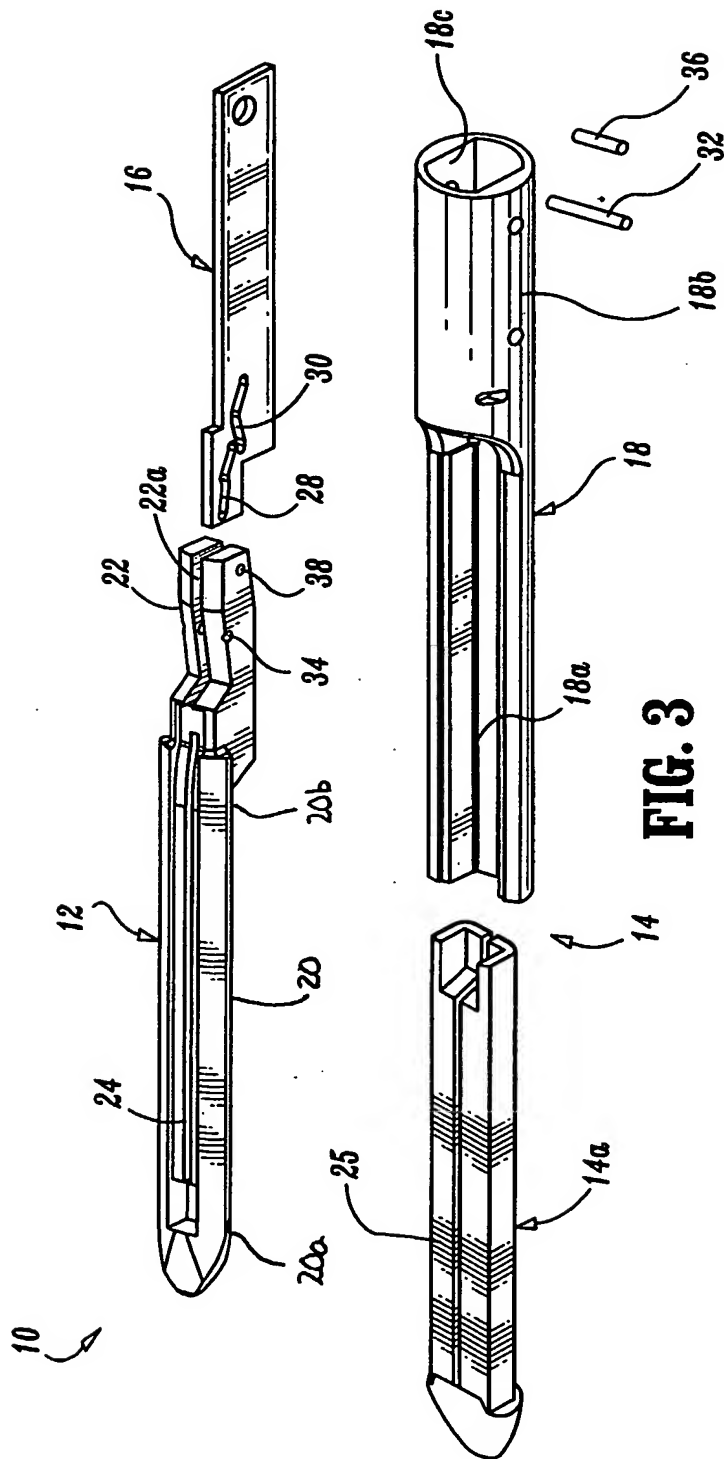


FIG. 2



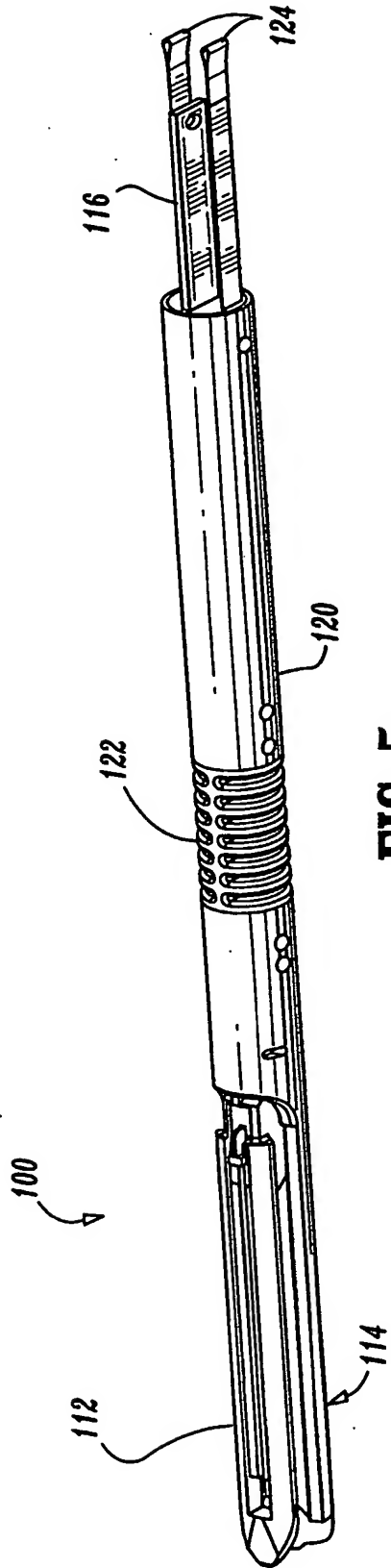


FIG. 5

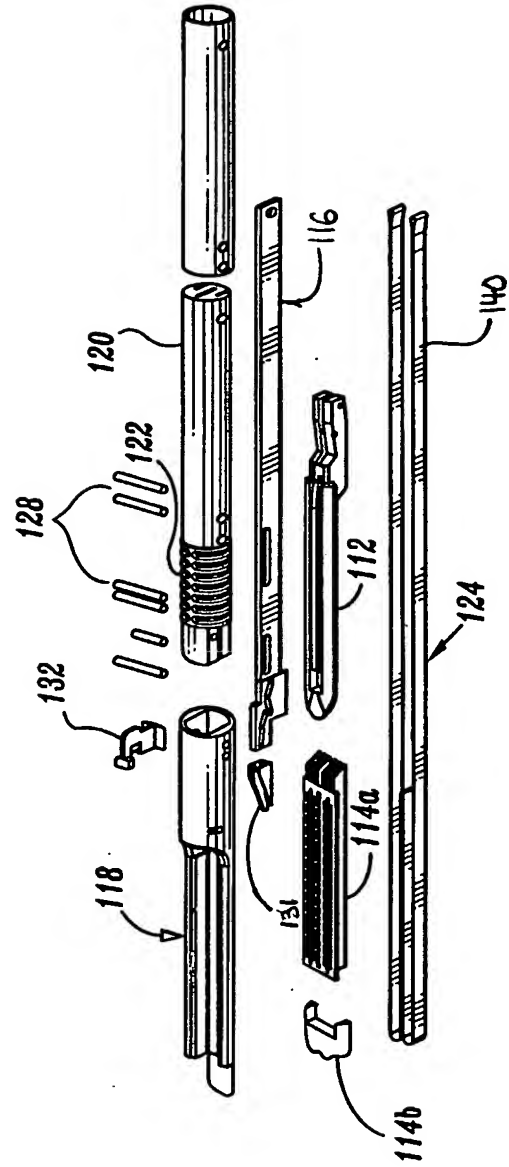
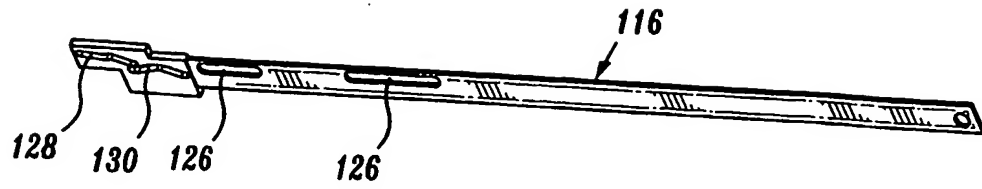
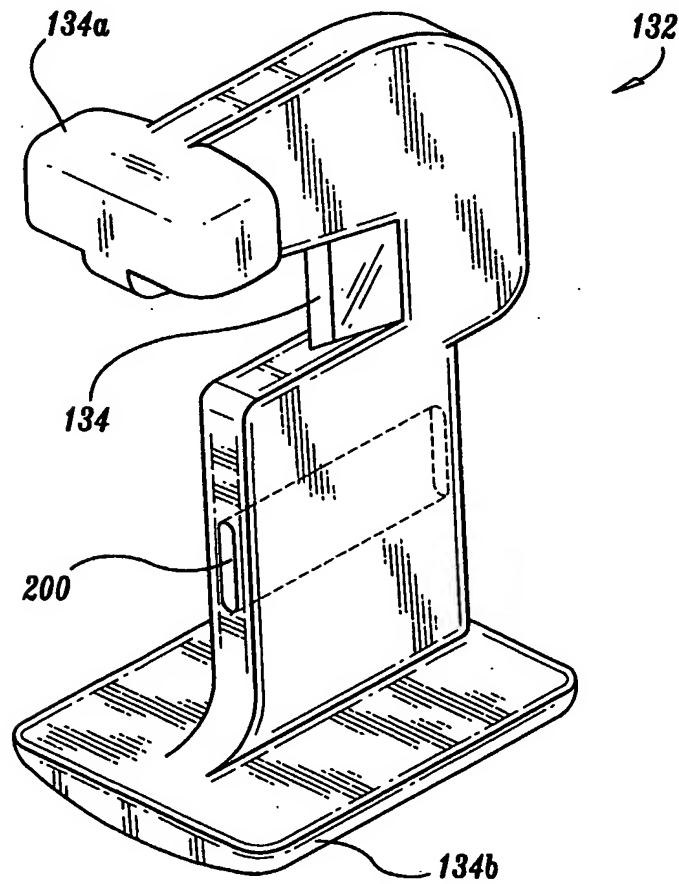


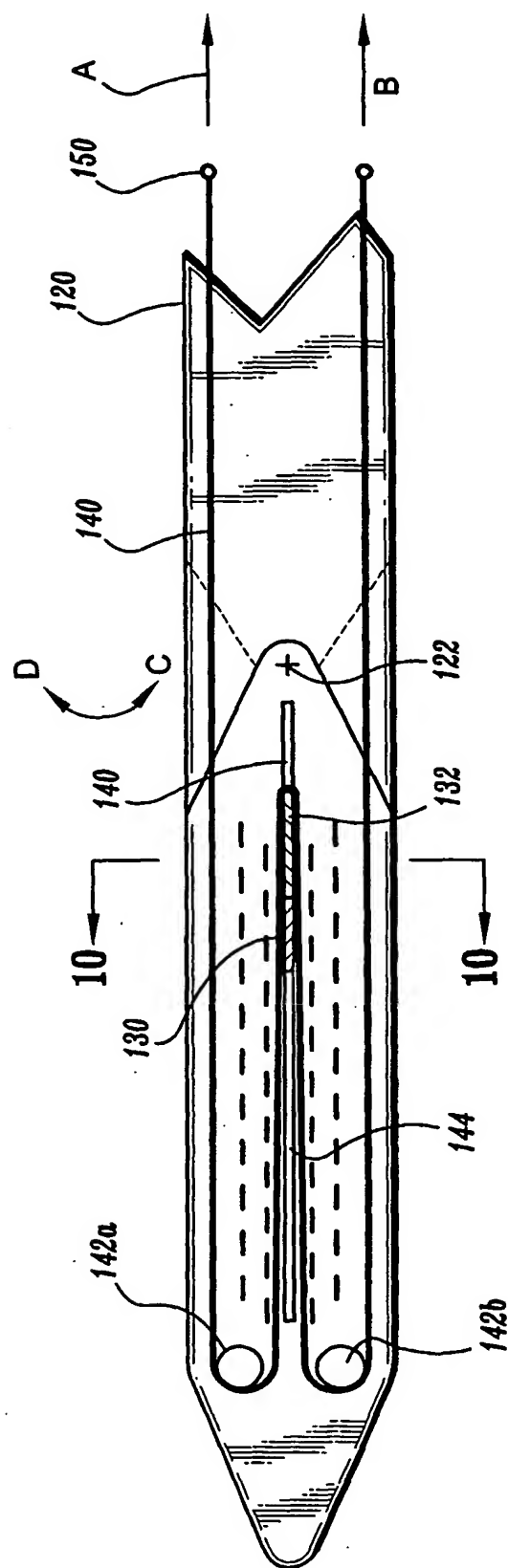
FIG. 6



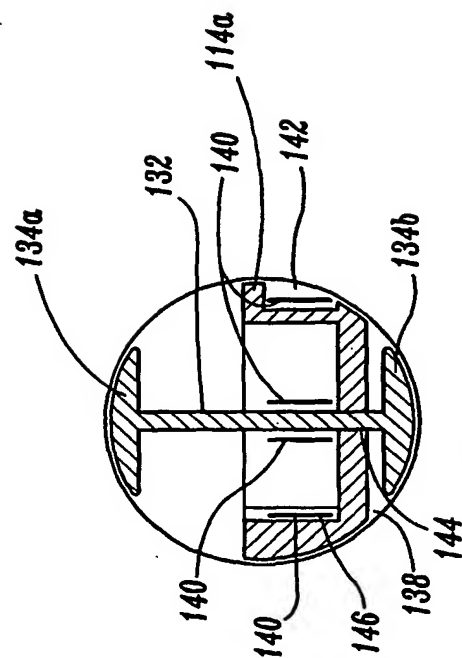
**FIG. 7**



**FIG. 8**



**FIG. 9**



**FIG. 10**